REMARKS

The amendment to the specification, amending the description of the Figures 7A and 7B does not add new matter. This amendment is fully supported by the disclosure in the specification as discussed in Section II herein. Accordingly, the amendment to the specification does not add new matter.

The amendments to the claims do not add new matter. Specifically, independent claims 45 and 65 have been amended to recite that the "shaped internal canal extending between said superior face and said inferior face" is a "**circular** shaped internal canal extending between said superior face and said inferior face." Support for this amendment is found in elected FIGS. 12A-12D. In addition, claims 45 and 65 have been amended to change the term "superior" face or surface to "upper" face or surface, and "inferior" face or surface to "lower" face or surface. Support for the terms "upper" and "lower" appear throughout the specification, including at page 9, lines 11-12 ("Alternatively, the implant is passed several times over a ridged surface which cuts the desired tooth profile into the upper, lower or both surfaces of the implant.") and at page 9, lines 19-20 ("The sharp anterior edge, like the teeth in the upper and lower surfaces of the implant, retards backing out of the implant."). Accordingly, this amendment does not add new matter.

The amendments adding new claims 67-71 do not add new matter. Claim 67 identically parallels amended claim 45 except that claim 67 recites that the "polygonal spinal spacer" is an "**eight-sided** polygonal spinal spacer" whereas claim 45 recites instead that the internal canal is "**circular**." Support for the term "eight-sided" is seen in elected FIG. 12A which shows that the elected spacer (like the spacers of FIGS. 13-17) is an eight-sided polygon. Accordingly, claim 67 is fully supported the specification as originally filed.

Claim 68, which recites that the "shaped internal canal" of the spacer of claim 67 is "circular" is supported by elected FIG. 12A. Claim 69, which recites that the "circular shaped internal canal contains a cancellous bone plug," is supported by the specification at page 20, lines 22-23 (In addition, where an osteogenic plug, such as a cancellous plug is present, this is shown in view E as a top view, and in view F as a side

view of the cancellous plug.") and at FIGS. 13A-13F, and at Table 1 at page 21 of the specification showing that the spinal spacers of FIGS. 12 and 13 have the same internal and external dimensions but that the spacer of FIG. 13 has a cancellous bone plug. Claim 70, which is directed to the "spinal spacer of claim 69, wherein said osteogenic bone plug is a cancellous bone plug" is supported by FIGS. 13A-13F, and by Table 1 at page 21 of the specification showing that the spinal spacers of FIGS. 12 and 13 have the same internal and external dimensions but that the spacer of FIG. 13 has a "cancellous plug."

Claim 71, which is directed to the eight sided spinal spacer of claim 67, wherein "said rows of migration resistant projections, ribbing or teeth occur on said superior vertebral engaging surface," is supported throughout the specification and by claim 53. Claim 72, which is directed to the eight sided spinal spacer of claim 67, wherein "wherein said posterior end has a beveled edge of defined radius," is supported throughout the specification, by claim 62, and by elected FIGS. 12 B and 12D (and parallel FIGS 13-17B and 13-17D) showing the eight-sided polygonal spacer with radius "R2".

For all these reasons, the amendments to the claims do not add new matter.

Bases for Objection/Rejection

The Patent Office requests clarification of the record regarding FIGS. 12A-12D.

The Patent Office objects to the Applicants' description of FIG 7 as allegedly introducing new matter in violation of 35 U.S.C. § 132.

Claim 65 is rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by Pafford.

Claims 45, 52-57, 60-62 and 66 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 6,371,988 (Pafford) in view of U.S. Pat. 5,888,222 (Coates).

The Applicants will address each of these bases for rejection in Sections I-IV, respectively, which follow.

I. Clarification of FIG. 12

The Patent Office requests clarification of the record regarding FIG. 12. In response to a request by the Patent Office, the Applicants amended originally filed FIG. 12 (corresponding to the elected embodiment and having FIGs. 12A-12D thereon) to include FIGs. 12E and 12F. In the Official Action of 02/18/04, the Patent Office changed its mind and said that the requested changes to FIG. 12 contained new matter and must be withdrawn. In the Applicants' response to the Official Action of 02/18/04, the Applicants requested by amendment that the Patent Office "delete previously submitted substitute FIG. 12 (having FIGs. 12A-12F thereon) and insert in its place original FIG. 12 (having FIGs. 12A-12D thereon)." In the present Official Action, the Patent Office request that the Applicants resubmit original FIG. 12, having FIGs. 12A-12D thereon. In response, the Applicants resubmit original FIG. 12 (having FIGs. 12A-12D thereon) as second substitute FIG. 12 and request that it substitute for substitute FIG. 12 (having FIGs. 12A-12F thereon). Therefore, this request has been satisfied.

II. Description of FIG. 7

The Patent Office objects to the Applicants' description of FIG 7 as allegedly introducing new matter in violation of 35 U.S.C. § 132. Specifically, the Patent Office alleges that the following language from the amendment is not supported by the original disclosure:

> FIG. 7A provides [sic] FIG 7B provides a side view of a stacked embodiment of two implants of FIG. 7A of this invention shown in juxtaposition.

The Applicants respectfully submit that the amendment does contain a typographical error and some missing text. The paragraph, as amended herein, is provided below:

> FIG. 7A provides a top view of implant 700 into which four holes have been drilled. FIG. 7B provides a side view of a stacked embodiment of two implants of FIG. 7A of this invention shown in juxtaposition with the drilled holes in register to receive pins that maintain the implants as a unitary body.

The Patent Office also contended in relation to the original paragraph that "The embodiment shown in figure 7B is **not in juxtaposition**, it is **stacked only**." [Official Action at page 3; emphasis added in bold.] The Applicants respectfully disagree. The specification discloses that it is both, *i.e.*, that the two pieces of the stacked embodiment are shown in juxtaposition (relative to their stacked arrangement):

> In **FIG. 7**, there is shown a further aspect of this invention in which an implant, either machined as described above, or prior to said machining, is further machined so as **to allow stacking** thereof to achieve implants of various heights. Commencing from a blank cortical plug at the stage shown in FIG. 2D has the advantage that if breakage of the implant occurs during machining, this will likely occur prior to completion of all of machining steps. According to this embodiment of the invention, **two implant blanks** of **known height** are selected such that a **unitary implant** composed of both starting implants can be produced of a new desired height (e.g. **a 6 mm high implant may be stacked with a 7 mm high implant to produce a 13 mm implant**). Each implant blank is placed in a drill jig, and by means of a drill press or like means, holes are drilled through the implants. With the implants still in the jig, the jig is placed on the table of an arbor press. Pins, composed of cortical bone, resorbable but strong biocompatible synthetic material, or metallic pins of the appropriate diameter are then impelled into the holes in the implants such that the implants are formed into a **unitary body** by these pins. In order to encourage bony ingrowth, channels may be cut into the adjacent surfaces of the implants. The embodiment shown in FIG. 7A is a top view of an implant 700 into which four holes 701-704 have been drilled. **In FIG. 7B, there is shown the *juxtaposition* of two implants 700A and 700B**, with the **drilled holes 701-704 in register to receive pins** for maintaining the implants in register. In this view, the adjacent surfaces 710A and 710B have not been inscribed with teeth, while the surfaces 711A and 711B have been so inscribed.
>
> [Specification at page 16, line 29 to page 17, line 16; emphasis added in bold.]

Thus, the specification expressly discloses that the terms "stacking" and "juxtaposition" are not mutually exclusive. Moreover, the specification discloses that these terms are fully supported in relation to the figures and in particular in relation to FIG. 7B. For all these reasons, this basis for the new matter objection has been rendered moot.

III. 35 U.S.C. § 102(e) over U.S. Pat. 6,391,988 (Pafford)

Claim 65 is rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by Pafford. According to the Patent Office, "Pafford et al teaches numerous embodiments of polygonal cortical spinal spacer." [Official Action at page 4.] The Patent Office then goes on to say that "figures 29-42 [of Pafford] teach[] a similar embodiment to applicant's figure 1 which applicant labels 'polygonal' by the limitation set forth in claim 58." The Applicants respectfully disagree.

In order to be anticipatory, each and every element of the claimed invention must be found in the cited prior art. Claim 65 of the Applicants' invention recites as follows:

> 65. (Currently amended) A polygonal spinal spacer for engagement between vertebrae, comprising: a polygonal cortical bone portion having an anterior end, an opposing posterior end, ~~a superior~~ upper face defining ~~a superior~~ an upper vertebral engaging surface and ~~an inferior~~ a lower face defining ~~an inferior~~ a lower vertebral engaging surface; said upper ~~superior~~ vertebral engaging surface, said ~~inferior~~ lower vertebral engaging surface, or both comprising **rows of migration resistant ribbing** extending from said surface; said rows of ribbing defining a pocket therebetween for trapping vertebral bone; said cortical bone portion further having a circular shaped internal canal extending between said ~~superior~~ upper face and said ~~inferior~~ lower face.
>
> [Emphasis added in bold.]

The relevant limitation is "rows of migration resistant ribbing." However, none of FIGS. 29-42 of Pafford disclose a polygonal spinal spacer with "rows of migration resistant ribbing extending from said surface." Specifically, FIGS. 29-32, 35-36 and 38 of Pafford disclose spinal implants with a smooth upper and lower surface, totally lacking in "rows of migration resistant ribbing extending from said surface." FIG. 33 of Pafford discloses a "collagen sponge" and not a spinal spacer. [Pafford at col. 5, line 20.] FIGS. 34 and 37 of Pafford disclose surgical instruments, *i.e.*, "an implant insertion device" [Pafford at col. 5, line 21] and "an implanting tool" [Pafford at col. 5, lines 25-25] and not a "spinal spacer" having "rows of migration resistant ribbing." FIG. 39 of Pafford disclosed a spinal implant with a "waffle pattern" on its surface. [Pafford at col. 13, lines 8-10 ("The roughened surface 191 of the spacer 190 may include a **waffle** or other suitable pattern as depicted in FIG. 39.");

emphasis added in bold.] Waffles are not ribs. Ask any restaurateur or Texan. FIG. 40 of Pafford discloses a spinal implant that has teeth. [Pafford at col. 13, lines 11-13 ("In one preferred embodiment shown in FIG. 40, the engaging surfaces 201 include **teeth** 205 which provide **biting** engagement with the endplates of the vertebrae."); emphasis added in bold.] Teeth are not ribs. This has been known since the days of Genesis when as the story goes, God made Eve from Adam's "rib," not his "tooth." FIGS. 41 and 42 of Pafford discloses a pair of "blades" on a surface of the implant. [Pafford at col. 13, lines 13-16 ("In another embodiment (FIGS. 41 and 42), the spacer 210 includes engaging surfaces 211 machined to include one or more blades 212. Each blade includes a cutting edge 213 configured to pierce a vertebral end-plate."); emphasis added in bold. The blades of FIGS. 41 and 42 of Pafford run in the anterior to posterior direction. In contrast, one skilled in the art recognizes that "ribs" run medially from side to side as the ribs in a person or in a sailing ship or as shown in Applicants' invention. For all these reasons, claim 65 would not be anticipated by any of FIGs. 29-41 of Pafford.

The Patent Office next asserts that "figures 2 and 24" of Pafford teach "polygonal" spacers. [Official Action at page 4.] The Applicants respectfully disagree. The ordinary meaning of a polygon is a flat shape with three or more straight lines:

> **polygon-** A closed **plane** figure bounded by three or more line segments.
>
> [Exhibit A: The American Heritage® Dictionary of the English Language, Fourth Edition, Copyright © 2000 by Houghton Mifflin Company. Published by Houghton Mifflin Company; emphasis added in bold.]

Thus, when the term "polygon" is given its ordinary meaning, it refers to a **planar** object. In contrast, the implants of FIGs. 2 and 24 of Pafford are **cylinders** and not planar or polygonal. For this reason, claim 65 would not be anticipated by the cylindrical implants of FIGs 2 and 24 of Pafford. Because Pafford fails to teach an implant that satisfies each and every element of claim 65 of Applicants' invention, claim 65 is not anticipated by Pafford.

IV. 35 U.S.C. § 103(a) over Pafford in view of Coates

Claims 45, 52-57, 60-62 and 66 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 6,371,988 (Pafford) in view of U.S. Pat. 5,888,222 (Coates). Claims 56 and 57 have been cancelled by amendment. Accordingly, only claims 45, 52-55, 60-62 and 66 remain subject to this basis for rejection.

According to the Patent Office, Pafford teaches "numerous embodiments of [a] polygonal cortical spinal spacer." [Official Action at page 4.] The Patent Office admits that "Pafford et al is silent regarding the rows of migration resistant projections angled towards the anterior end of the spacer." [Official Action at page 4.] To make up for this deficiency, the Patent Office cites to Coates. However, independent claims 45 and (non-obvious) claim 65 have been amended to recite that the "shaped internal canal extending between said superior face and said inferior face" is a "a circular shaped internal canal extending between said superior face and said inferior face." Claims 52-55, 60-62 and 66, which recite dependency from claims 45 and 65 incorporate this recitation by reference to those claims. All of the planar and polygonal implants of Pafford and Coates are "D" shaped on the exterior and each has a "D" shaped internal canal extending from the upper surface to the lower surface. Neither Pafford nor Coates teaches or suggests the circular internal canal of the Applicants' invention. The circular internal canal of the Applicants' invention facilitates the Applicants' use of a cancellous plug (*e.g.*, Applicants' FIGS 13, 15 and 17) which is more easily made in a circular form than in a "D" shaped form and which can be inserted in the corresponding circular canal in any orientation.

For all these reasons, claims 45, 52-55, 60-62 and 66 would not have been obvious over Pafford in view of Coates. The allowance of claims 45, 52-55, 60-62 and 66 is respectfully requested.

New claims 67-72, which include a recitation that the polygonal spinal spacer is "eight-sided," are separately patentable over Pafford or Coates, alone or in combination, because neither Pafford nor Coates teach or suggest an eight sided polygonal spinal spacer. The allowance of claims 67-72 is respectfully requested.

CONCLUSION

Claims 45-66 were initially pending. Claims 56-57 and withdrawn claims 46-51, 58-59 and 63-64 were cancelled by amendment herein. Claims 67-72 were added. Hence claims 45, 52-55, 60-62, and 65-72 are pending.

In view of the substitute FIG 12 cofiled herewith, the clarification of the record has been made. In view of the arguments and evidence submitted herein, the new matter rejection has been rebutted. In view of the arguments herein, the rejection of claim 65 under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,371,988 (Pafford) has been rebutted and or rendered moot. In view of the amendments and arguments herein, the rejection of claims 45, 52-55, 60-62, and 66 under 35 U.S.C. § 103(a) over Pafford in view of Coates has been rebutted.

Finally, new claims 67-72, which include a recitation that the polygonal spinal spacer is "eight-sided," are separately patentable over Pafford or Coates, alone or in combination, because neither Pafford nor Coates teach or suggest an "eight sided" polygonal spinal spacer.

For all these reasons, the allowance of claims 45, 52-55, 60-62, and 65-72 is respectfully requested.

Respectfully submitted,

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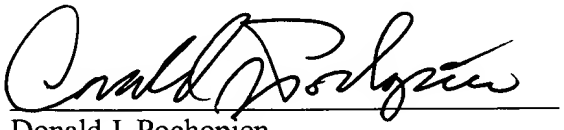
By: 

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Dictionary -

3 entries found for *Polygon.*

pol·y·gon (pŏl'ē-gŏn')
n.

A closed plane figure bounded by three or more line segments.

po·lyg'o·nal (pə-lĭg'ə-nəl) *adj.*
po·lyg'o·nal·ly *adv.*

[ ]
: *The American Heritage® Dictionary of the English Language, Fourth Edition*

Polygon

n : a closed plane figure bounded by straight sides [syn:
]

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